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|-----------------|-------------|----------------------|---------------------|------------------|
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10/628,066

07/25/2003

Prancla Rameshwar

4164

26259

7590

05/16/2007

LICATA & TYRRELL P.C.  
66 E. MAIN STREET  
MARLTON, NJ 08053

EXAMINER

YU, MISOOK

ART UNIT

PAPER NUMBER

1642

MAIL DATE

DELIVERY MODE

05/16/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

**Application No.**

10/628,066

**Applicant(s)**

RAMESHWAR ET AL.

**Examiner**

MISOOK YU, Ph.D.

**Art Unit**

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 26 February 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2,6,13,14 and 18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,2 and 6 is/are allowed.
- 6) ☒ Claim(s) 13,14 and 18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input checked="" type="checkbox"/> Other: <u>Exhibit A (sequence alignment)</u>     |

### DETAILED ACTION

Claims 1, 2, 6, 13, 14, and 18 are pending and under consideration.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 13, 14, and 18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This written description rejection is maintained because claim 13 is interpreted as drawn to a genus of nucleic acid molecules comprising a fragment of at least 500 contiguous nucleotides of SEQ ID NO:1, wherein said fragment has promoter activity, and includes the recited CMP element. This includes a whole universe of nucleic molecules with any promoter activity in genome of any living organism. The dependent claim 14 and 18 are further drawn to isolated vectors and host cells comprising the above whole universe of sequences. The specification teaches at Figure 3 and Example 11 at page 59 that the DNA sequences of SEQ ID:1, 14, and a fragment named as N1 have promoter activities. Based on these two human PPT-1 promoters and the fragment N1, one cannot predict the types of additional DNA molecules of at least 500 contiguous nucleotides of SEQ ID NO:1. Since the genus includes a large

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number of unpredictable species, for example promoters from mouse and other organism, possession of only three species is not seen as sufficient to reasonably convey possession of the entire genus of DNA molecules with at least 500 nucleotides of SEQ ID NO:1. It is concluded that applicants adequately describes SEQ ID NO:1 and 14, and N1.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 13, 14 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Gilchrist et al., DNA Cell. Biol., 1991 Dec;10(10):743-9 (A7 of IDS filed on 3/8/2004) as evidenced by GenEmbl accession number S69719, May 7, 1993 (A6 of IDS filed on 3/8/2004)

Claims 13, 14 and 18 are drawn to nucleic acid molecules comprising a fragment of at least 500 contiguous nucleotides of SEQ ID NO:1, wherein said fragment has promoter activity and includes a CAMP response element having TTCCGTCA, and an isolated vector comprising the nucleic acid, and an isolated host cell transformed with the vector. The limitation “a fragment of at least 500 contiguous nucleotides of SEQ ID NO:1” is interpreted as any size fragment obtained from at least 500 contiguous nucleotides of SEQ ID NO:1.

Gilchrist et al., teaches "transfected PC12 cells and F11 cells with plasmids containing the bovine PPT promoter linked to the reporter gene chloramphenicol acetyltransferase (CAT)." GenEmbl accession number S69719 teaches a DNA molecule comprising a fragment at least 500 contiguous nucleotides of SEQ ID NO:1, wherein said DNA molecule is a 5' promoter region of bovine PPT gene, whose sequence came from Gilchrist et al. GenEmbl accession number S69719 was constructed from Gilchrist et al (DNA Cell Biol 10, 743-749). The plasmids containing the bovine PPT promoter as disclosed in Gilchrist et al., includes a CAMP response element having TTGCGTCA. Note nucleotides #1534-1541 of GenEmbl accession number S69719, which contains the CAMP response element having TTGCGTCA. Note the boxed area at page 1 of the attached sequence alignment.

***Allowable Subject Matter***

Claims 1, 2, 6 are allowed.

***Conclusion***

Any rejection not repeated here is withdrawn.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory

action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 571-272-0839. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



MISOOK YU, Ph.D.  
Primary Examiner  
Art Unit 1642

Exhibit A

<!--StartFragment-->RESULT 12 of seq 10 no: 1

S69719

LOCUS S69719 1890 bp DNA linear MAM 07-MAY-1993

DEFINITION preprotachykinin (PPT) {5' region} [cattle, Genomic, 1890 nt].

ACCESSION S69719

VERSION S69719.1 GI:240311

KEYWORDS .

SOURCE Bos taurus (cattle)

ORGANISM Bos taurus

Eukaryota; Metazoa; Chordata; Craniata; Vertebrata; Euteleostomi; Mammalia; Eutheria; Laurasiatheria; Cetartiodactyla; Ruminantia; Pecora; Bovidae; Bovinae; Bos.

REFERENCE 1 (bases 1 to 1890)

AUTHORS Gilchrist,C.A., Morrison,C.F., Chapman,K.E. and Harmar,A.J.

TITLE Identification of nerve growth factor-responsive sequences within the 5' region of the bovine preprotachykinin gene

JOURNAL DNA Cell Biol. 10 (10), 743-749 (1991)

PUBMED 1741955

REMARK GenBank staff at the National Library of Medicine created this entry [NCBI gibbsq 69719] from the original journal article.

FEATURES

Location/Qualifiers

source 1..1890

/organism="Bos taurus"

/mol\_type="genomic DNA"

/db\_xref="taxon:9913"

gene 1..1890

/gene="preprotachykinin (PPT)"

ORIGIN

Query Match 26.7%; Score 343.2; DB 14; Length 1890;

Best Local Similarity 75.5%; Pred. No. 2.4e-100;

Matches 572; Conservative 0; Mismatches 143; Indels 43; Gaps 10;

Qy 116 CTAAGGAAAAGCCAGTATTCGCGTTGATTTAGAAGAGGGATGTTCTGGTTATAGAACGAT 175

| || || || || || || || || || || || || || || || || || || || || || || || || || ||

Db 1148 CAAAAAACCGCCAGTATTCTAGTTGGTTTGAGAGAAGGTTGTTCTGCTCACAGAAAGAT 1207

Qy 176 GCTGTGTCTCAGAAACACTTAA-ATACTATTAAGCTAGAAATAGAAGGGAAAATAATGCT 234

| || || || || || || || || || || || || || || || || || || || || || || || || || ||

Db 1208 GTTGTATCTCAGAAACACTTAAGATACTCTGCAGACGGAAATAGGGGGGAATGCC----- 1262

Qy 235 TCCCCGCATCTCCCTCAAGTGTAGTCCTCTTTTTTTAGCCTGATTTCCGACGAAATGTC 294

| || || || || || || || || || || || || || || || || || || || || || || || || || ||

Db 1263 -----CCCCCCCATTGGAGTTCTCCTTCTTAGCCTGATTTCCGAC--AATATT 1311

Qy 295 TGAATGCCTACAGTTATTTGGCCATCCTGAAAAGTGCAACTTATCCTGACGTCTCGAGGG 354

| || || || || || || || || || || || || || || || || || || || || || || || || || ||

Db 1312 TTAATATCTGAAGTTATTTGGCCATCCTTAGAAGTGCAACGTATCC-----TCTCATGGC 1366

Qy 355 ACGGAAAAGTTACCGAAGTCCAAGGAATGAGTCACTTTGCTCAAATTTGATGAGTAATAT 414

| || || || || || || || || || || || || || || || || || || || || || || || || || ||

Db 1367 ACGAAAAGTTGCCTAAGTCCGAGGAATGAGTCACTTTGC-----TTTGATGAGTAATCT 1421

Qy 415 CAGGTGTCATGAAACCCAGTTTCGAAG-GAGAGGGGAGGGGGCGTCAGATCTGCAGACGG 473

| || || || || || || || || || || || || || || || || || || || || || || || || || ||

Db 1422 TAGGTGTCATGGAACCTCGTTCGGAAGAAAGAGGGGAGGGGGCGTCAGATATGCCTACGG 1481

Qy 474 AAGCAGGCCGCTC-----CGGATTGGATGGCGAGACCTCGATTTTCTAAATTTGCGTCA 528

| || || || || || || || || || || || || || || || || || || || || || || || || || ||

Db 1482 AAGAAGACAGGCCGCTGGGTTATTGGATGGCGAGAACTCGATATTCCTATAATTGCGTCA 1541

cAMP

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<!--EndFragment-->
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